ONO PHARMACEUTICAL CO.,LTD.

July 30, 2018

ONO Submits Supplemental Application of ONOACT® for Intravenous Infusion 50mg・150mg, Short-Acting Selective β_1 Blocker for Indication of Ventricular Arrhythmia for a Partial Change in Approved Items of Manufacturing and Marketing Approval in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President, Representative Director: Gyo Sagara; "ONO") announced today that it submitted a supplemental application of ONOACT® (landiolol hydrochloride) for Intravenous Infusion 50mg・150mg ("ONOACT"), a short-acting selective β_1 blocker for indication of ventricular arrhythmia for a partial change in the approved items of the manufacturing and marketing approval in Japan.

This application is based on the result of a multi-center, open-label, non-comparative study, late Phase Ⅱ/Ⅲ study (ONO-1101-30), conducted in Japan, in patients with recurrent ventricular arrhythmia.

Ventricular arrhythmia that occurs in the ventricle responsible for pumping blood to the whole body is classified as ventricular tachycardia (VT) and ventricular fibrillation (VF). Since ventricular arrhythmia is fatal one that causes sudden cardiac death, it is necessary to stop the arrhythmia by electrical defibrillation as soon as possible on occurrence and to prevent the recurrence of ventricular arrhythmia afterwards. It is known that the ventricular arrhythmia is related with enhanced sympathetic nerve activity in the ventricle in pathogenic mechanism.

ONOACT is the short-acting selective β_1 blocker which relaxes the tension of sympathetic nervous by selectively blocking β_1 receptor existing mostly in the heart, and prevents the recurrence of ventricular arrhythmia. It is expected that ONOACT can contribute in the therapy of fatal arrhythmia requiring emergency treatment. In addition, in August 2016, the product was designated as an orphan drug by the MHLW for the indication of "refractory and urgent fatal arrhythmia; VF and hemodynamically unstable VT".

ONOACT, discovered and developed internally by ONO, was approved for emergency treatment of intra-operative tachyarrhythmia (atrial fibrillation, atrial flutter and sinus tachycardia) in July 2002. Then, it was also approved for additional indication of emergency treatment of post-operative tachyarrhythmia (atrial fibrillation, atrial flutter and sinus tachycardia) with monitoring of circulatory dynamics in October 2006 and for treatment of tachyarrhythmia (atrial fibrillation and atrial flutter) in left ventricular dysfunction in November 2013. ONOACT has been widely used so far in lots of these patient populations.

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